DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M2983n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 99-NWJ-37

September 17, 1999

Mr. Brant F. Gibbs, Owner
Mr. Keith H. Gibbs, Owner
Mr. Frank H. Gibbs, Owner
Gibbs Quest Dairies
164 Johnsonburg Road
Andover, NJ 07821

Dear Messrs. Gibbs:

An investigation at your dairy farm, located at Andover, NJ, conducted by our investigator on August 17 and August 23, 1999, confirmed that you offered a dairy cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii), 402(a)(4), and 402(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about 6/15/99 you sold a dairy cow, identified with tag number #4512, for slaughter as human food at the Livestock Co-Operative Auction Market, Association of North Jersey, Inc., Hackettstown, NJ. This animal was then sold by [redacted] to [redacted], [redacted]. United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 1.30 parts per million (ppm) of sulfadimethoxine in the liver tissue. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the uncooked, edible tissues of cows (Title 21 Code of Federal Regulations Part 556.640). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions inadequate to prevent diseased and/ or medicated animals bearing potentially harmful drug residues from entering the food supply. For example you failed to withhold the animal in question (tag #4512) from slaughter for a sufficient time to permit depletion of any potentially hazardous residue of sulfadimethoxine from edible tissues, as the instructions for use of the drug indicated. In addition, you did not maintain a system of medication and treatment records that, at a minimum, identify the treated animal, date(s) of treatment, drug(s)

administered, person(s) administering the drug(s), and the withdrawal time prior to slaughter. Further, although Dr. Bockbrader supplied a labeled bottle of ALBON LIQUID (sulfadimethoxine) to you, which included drug identification and directions for withdrawal times, your establishment failed to maintain this product labeling. Instead, this prescription drug product was being stored for use, without labeling of any kind.

Our investigation also revealed that you are adulterating the drug ALBON LIQUID (sulfadimethoxine) that your firm used to treat the animal in question within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Your use of the drug, without following the labeled withdrawal period, causes the drug to be unsafe for use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration Attention Christine M. Marmara, Acting Compliance Officer, at the address and telephone number listed above.

Sincerely yours,

Roy Abrahams for

Douglas I. Ellsworth
District Director
New Jersey District